



1632  
ITV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Roland BUELOW, et al.

Application Serial No. 09/921,819

Filed: August 3, 2001

For: **PRODUCTION OF HUMANIZED  
ANTIBODIES IN TRANSGENIC  
ANIMALS**

) Examiner: Wehbe, Anne Marie Sabrina

) Art Unit: 1632

) Attorney's Docket No. 39691-0005A

) Customer No. 25213

**EXPRESS MAIL LABEL NO. EL 993 691 901 US**  
Date Mailed: **OCTOBER 25, 2004**

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.97**

**MAIL STOP AMENDMENT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Listed below or on an attached Form PTO-1449 is information known to applicant(s). A copy of each listed publication and U.S. and foreign patent, except for pending U.S. applications, is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

☐ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):

- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --
- ☐ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

☒ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

- ☐ a certification as specified in §1.97(e) is provided below; or
- ☒ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; and
- C. a fee of \$180.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

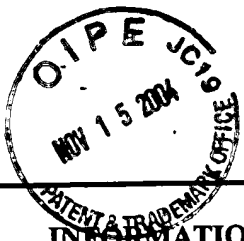
☒ **Fee Authorization.** The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 08-1641 (Attorney's Docket No. 39691-0005A).

Respectfully submitted,

Dated: October 25, 2004

By: Daphne Reddy  
Daphne Reddy (Reg. No. 53,507)

**HELLER EHRMAN WHITE & MCAULIFFE LLP**  
275 Middlefield Road  
Menlo Park, California 94025-3506  
Telephone: (650) 324-7000 / Facsimile: (650) 324-0638



**INFORMATION DISCLOSURE  
STATEMENT**

**PTO-1449**

**ATTY. DOCKET NO.:**

**39691-0005A**

**SERIAL NO.:**

**09/921,819**

**APPLICANT : Roland BUELOW, et al.**

**FILING DATE: August 3, 2001**

**GROUP: 1632**

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	5,202,238	04/13/1993	Fell, Jr. et al.	435	69.6	

**FOREIGN PATENT DOCUMENTS**

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 99/10505	03/04/1999	PCT	C12N	15/62	<input type="checkbox"/>	<input type="checkbox"/>
	WO 00/46251	08/10/2000				<input type="checkbox"/>	<input type="checkbox"/>
	WO 01/19394	03/22/2001	PCT	A61K	67/027	<input type="checkbox"/>	<input type="checkbox"/>

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	Akimenko, M.A., "Rabbit immunoglobulin b9 C kappa light chain gene", June 13, 1985.
<i>Forthcoming</i>	Akimenko, M.A., "Complex allotypes of the rabbit immunoglobulin kappa light chains are encoded by structural alleles", Nucleic Acids Research, Vol. 12, No. 11, pp 4691-4701, 1984.
	Andris-Widhopf, J. et al., "Methods for the generation of chicken monoclonal antibody display", Journal of Immunological Methods, Vol. 242, pp 159-181, August 28, 2000.
	Butler, J E, "Immunoglobulin diversity B-cell and antibody repertoire development in lar", Scientifique et Technique Office International Des Epizooties, Vol. 17, No. 1, pp 43-70,
	Clarkson C.A., "O.aries mRNA for Ig gamma 2 constant region heavy chain", Database March 10. 1993.
	Clarkson C.A., et al., "Sequence of ovine Ig gamma-2 constant region heavy chain cDN modeling of ruminant IgG isotypes, Molecular Immunology, Vol. 30, No. 13, pp. 1195-....., .....
	Dreher, K. L., et al., "Rabbit IG Kappa-1B6 Gene Structure", Journal of Immunology, Vol. 145, No. 1, pp 325-330, July 1, 1990.
	Dufour, V., "O.aries mRNA for immunoglobulin gammal chain secreted form", Database Accession No. X69797, December 23, 1992.
	Dufour, Vinciane, et al., "The Sheep Ig Variable Region Repertoire Consists of a single V <sub>H</sub> family", Journal of Immunology, Vol. 156, No. 6, pp 2163-2170, 1996.
	Green, L.L., "Antibody engineering via genetic engineering of the mouse: XenoMouse strains are a vehicle for the facile generation of therapeutic human monoclonal antibodies", Journal of Immunological Methods, Vol. 231, No. 1-2, pp 11-23, December 10, 1999.
EXAMINER	DATE CONSIDERED

*Attached*

*Thank you!*

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



<b>INFORMATION DISCLOSURE STATEMENT</b>  <b>PTO-1449</b>	<b>ATTY. DOCKET NO.:</b> 39691-0005A	<b>SERIAL NO.:</b> 09/921,819
	<b>APPLICANT :</b> Roland BUELOW, et al.	
	<b>FILING DATE:</b> August 3, 2001	<b>GROUP:</b> 1632
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>		
	Kacskovics, "Bos taurus IgG1 heavy chain constant region (IgC-gamma) mRNA, partial cds", Database Accession No. S82409, December 7, 1996.	
	Kacskovics, Imre et al., The Heterogeneity of Bovine IgG2: VIII. The Complete cDNA Sequence of Bovine IgG2a (A2) and an IgG1", Molecular Immunology, Vol. 33, No. 2, pp 189-195, 1996.	
	Jackson, T. et al., "B. taurus mRNA for Immunoglobulin G1 heavy chain", Database Accession No. X62916.1, June 17, 1992.	
	Jackson, T. et al., "Nucleotide Sequences and Expression of CDNAS for a Bovine Anti-Testosterone Monoclonal IGG1 Antibody", Molecular Immunology, Vol. 29, No. 5, pp 667-676, 1992.	
	Mariame, B. et al., "Interallelic and intergenic conversion events could induce differential evolution of the two rabbit immunoglobulin kappa light chain genes", Nucleic Acids Research, Vol. 15, No. 15, August 11, 1987.	
	Martens, C.L. et al., "Oryctolagus cuniculus Ig gamma H-chain C-region gene, partial cds", Database Accession No. L29172, March 2, 1994.	
	Martens, C.L., "Molecular Genetic Analysis of Genes Encoding the Heavy Chains of Rabbit Immunoglobulin G", Journal of Immunology, Vol. 133, No 2, pp 1022-1027, 1984.	
	Rader, C et al., "The Rabbit Antibody Repertoire as a Novel Source for the Generation of Therapeutic Human Antibodies", Journal of Biological Chemistry, Vol. 275, No. 18, pp 13668-13776, May 5, 2000.	
	Symons et al., "Bovine Ig germline heavy chain gamma-2-chain gene C-region, 3' end", Database Accession No. X16702, November 23, 1989.	
	Symons et al., " Structure of Bovine Immunoglobulin Constant Region Heavy Chain Gamma 1 and Gamma 2 Genes", Molecular Immunology, Vol. 26, No. 9, pp 841-850, 1989.	
	Taki, Shinsuke et al., "Targeted insertion of a variable region gene inot the immunoglobulin heavy chain locus", Science, Vol. 262, No. 5137, pp 1268-1271, 1993.	
	Weidle U H et al., "Genes Encoding a Mouse Monoclonal Antibody Are Expressed in Transgenic Mice, Rabbits and Pigs", Gene, Vol. 98, No. 2, pp. 185-191, February 15, 1991.	
	Winstead, C. R. et al., "Antigen-induced somatic diversification of rabbit IgH genes: gene conversion and point mutation", Journal of Immunology, Vol. 162, No. 11, June 1, 1999.	
	Yarnold, S. et al., "Chimerization of Antitumor Antibodies via Homolgous Recombination Conversion Vectors", Cancer Research, American Association for Cancer Research, Vol. 54, No. 2, pp 506-512, January 15, 1994.	
	Zou, Yong-Rui et al., "Generation of a mouse strain that produces immunoglobulin kappa chains with human constant regions", Science, Vol. 262, No 5137, pp 1271-1274, 1993.	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



RECEIVED BY THE U.S. PATENT AND TRADEMARK OFFICE:

EXPRESS MAIL NO. EL 993 691 901 - DATE MAILED: OCTOBER 25, 2004  
Attorney's Docket No. 39691-0005 A (GRD:DR:sp)

Applicant(s): Roland BUELOW, et al.  
Title: PRODUCTION OF HUMANIZED ANTIBODIES IN TRANSGENIC ANIMALS

Application Serial No. 09/921,819 Group Art Unit: 1632  
Filing Date: August 3, 2001 Examiner: Wehbe, Anne Marie Sabrina

Commissioner for Patents - MAIL STOP AMENDMENT  
PO Box 1450  
Alexandria, Virginia 22313-1450

SIR:

Please place the U.S. Patent and Trademark Office date stamp hereon to acknowledge receipt of the following:

1. Information Disclosure Statement;
2. PTO 1449 with 29 references (from Partial European Search Report); and
3. Return Postcard.

EL 993691901 US



EL 993691901 US

Mailing Label  
Label 11-F June 2002



UNITED STATES POSTAL SERVICE®

Post Office To Addressee

ORIGIN (POSTAL USE ONLY)			DELIVERY (POSTAL USE ONLY)		
PO ZIP Code	Day of Delivery <input type="checkbox"/> Next <input type="checkbox"/> Second	Flat Rate Envelope <input type="checkbox"/>	Delivery Attempt	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Date In Mo. Day Year	<input type="checkbox"/> 12 Noon <input type="checkbox"/> 3 PM	Postage \$	Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Time In <input type="checkbox"/> AM <input type="checkbox"/> PM	Military <input type="checkbox"/> 2nd Day <input type="checkbox"/> 3rd Day	Return Receipt Fee	Delivery Date	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Weight lbs. ozs.	Int'l Alpha Country Code	COD Fee Insurance Fee	Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	
No Delivery <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday	Acceptance Clerk Initials	Total Postage & Fees \$	<input type="checkbox"/> WAIVER OF SIGNATURE (Domestic Only) Additional merchandise, services, or fees if waiver of signature is requested. I wish delivery to be made without signature of addressee or addressee's agent (if delivery employee judges that person is not at correct location) and I authorize that delivery employee's signature be used.		
CUSTOMER USE ONLY METHOD OF PAYMENT: Express Mail Corporate Acct. No. <b>X940466</b>			NO DELIVERY <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday		
Federal Agency Acct. No. or Postal Service Acct. No.					
FROM: (PLEASE PRINT) <b>PATENT &amp; TRADEMARK GROUP HELLER EHRMAN WHITE &amp; MCAULIFFE, LLP 275 MIDDLEFIELD RD. MENLO PARK CA 94025-3506</b> PHONE <b>650 324 7000</b> <b>39691-0005 (GRD:DR:sp)</b>			TO: (PLEASE PRINT) <b>MAIL STOP Amendment COMMISSIONER FOR PATENTS PO BOX 1450 ALEXANDRIA VA 22313-1450</b> PHONE ( )		

PRESS HARD.  
You are making 3 copies. FOR PICKUP OR TRACKING CALL 1-800-222-1811 www.usps.com

DOCKETED